Response to FDA Request for Additional Information dated February 26, 2009

SECTION 5: 510(k) SUMMARY

Silver Impregnated Hydrofiber® Dressing Reinforced with Nylon (Flat)

Applicant: ConvaTec Inc.
200 Headquarters Park Drive
Skillman, New Jersey 08558

SEP – 4 2009

Contact: Patricia Kearins
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Device: Silver Hydrofiber® Dressing Reinforced with Nylon (Flat)

Classification Name: Dressing, Wound, Drug

Device Class: Unclassified

Product Code: FRO

Substantially Equivalent Device: AQUACEL Ag Hydrofiber® Wound Dressing - K080383

Silver Hydrofiber® Reinforced with Nylon Wound Dressings is a soft, sterile, non-woven flat dressing composed of hydrocolloid fibers (sodium carboxymethylcellulose), that is reinforced with nylon stitching and that contain 1.2% ionic silver which allows for an average of 12mg of silver for a 4 inch x 4 inch dressing. The silver in the dressing kills wound bacteria held in the dressing and provides an antimicrobial barrier to protect the wound bed. This dressing absorbs high amounts of wound fluid and bacteria and creates a soft, cohesive gel that intimately conforms to the wound surface, maintains a moist environment and aids in the removal of non-viable tissue from the wound (autolytic debridement). The moist wound healing environment and control of wound bacteria supports the body's healing process and helps reduce the risk of wound infection.

Silver Hydrofiber® Reinforced with Nylon flat dressings are indicated for the management of wounds and can be used under the supervision of a healthcare professional for the management of: partial thickness (second degree) burns; diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness); wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection; surgical wounds left to heal by secondary intention such as dehisced surgical incisions; surgical wounds that heal by primary intention such as dermatological and surgical incisions (e.g., orthopedic and vascular); traumatic wounds; wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites;

oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma; management of painful wounds and infected wounds.

These indications are identical to those of the predicate device, K080383, AQUACEL® Ag Hydrofiber Dressing.

Extensive clinical testing, including controlled GCP studies, has been carried out with AQUACEL® Ag (the predicate). The results of these studies have consistently demonstrated that the products are safe and effective dressings in the treatment of a wide range of wound types. The fluid handling and gelling properties of AQUACEL® Ag have been shown to provide patient benefits in terms of exudate management, comfort, (comparative) pain reduction on dressing changes, control of peri-wound maceration, non-adherence and moist wound healing. See 510(k) #K080383 for details. Silver Hydrofiber® Dressing Reinforced with Nylon is essentially the same base fabric as AQUACEL® Ag, with the addition of Nylon stitching incorporated to reinforce the dressing.

In view of the breadth of evidence to support the clinical safety and performance of sodium carboxymethylcellulose fiber (in particular AQUACEL®) in a wide range of wounds, the well known and accepted antimicrobial profile of silver and the established clinical use of silver containing AQUACEL® Ag dressings, together with clinical data relevant to this product, extensive clinical investigations with Silver Hydrofiber® Dressings Reinforced with Nylon were not considered necessary to confirm the clinical safety and performance for all indications, however, a single study has been carried out in partial thickness burns, which is anticipated to be the major indication for this product due to the need for flexibility of a dressing as the wound dries out. This study is detailed in Section 20: Performance Testing-Clinical of K090254.

Based on the history of use of the predicate device and the above referenced clinical study, it is concluded that Silver Hydrofiber® Dressing Reinforced with Nylon is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP - 4 2009

ConvaTec, Inc.
% Ms. Patricia Kearins
Manager, Regulatory Affairs
200 Headquarters Park Drive
Skillman, New Jersey 08558

Re: K090254
Trade/Device Name: Silver Impregnated Hydrofiber® Dressing Reinforced with Nylon (Flat)
Product Code: FRO
Dated: August 19, 2009
Received: August 20, 2009

Dear Ms. Kearins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Response to FDA Request for Additional Information dated February 26, 2009

Section 4: Indications for Use Statement

510(k) Number (if known): **K090254**

Device Name: Silver Impregnated Hydrofiber® Dressing Reinforced with Nylon (Flat)

Indications for Use:

Under the supervision of a healthcare professional, the Silver Hydrofiber® Wound Dressing Reinforced with Nylon may be used for the management of:

- Partial thickness (second degree) burns;
- Diabetic foot ulcers, leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial and full thickness);
- Wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection;
- Surgical wounds left to heal by secondary intention such as dehisced surgical incisions;
- Surgical wounds that heal by primary intention such as dermatological and surgical incisions (e.g., orthopedic and vascular)
- Traumatic wounds
- Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites
- Oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma and angiosarcoma
- Management of painful wounds
- Infected wounds

Prescription Use X
(21 CFR 801 Subpart D)

Over-the-Counter Use ____
(21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH; Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090254